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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,576	08/09/2001	Carsten Andersen	10004.204-US	2881

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NOVOZYMES NORTH AMERICA, INC.
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NEW YORK, NY 10110

EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/925,576

Applicant(s)

ANDERSEN ET AL.

Examiner

Elizabeth Slobodyansky, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-30,50,57 and 59-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-30,50,57 and 59-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2007 has been entered.

The AF amendment filed August 23, 2007 amending claims 25-29, 50 and 57 and adding claims 59-66 has been entered.

Claims 25-30, 50, 57 and 59-66 are pending.

Claim Objections

Claims 25 and 59 are objected to as containing parenthesis.

Claims 59-66 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 25-30, 50 and 57. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29 and 63 are drawn to a variant alpha-amylase comprising triple substitution R118K, R320K and R458K. While there is support in the specification for each of said substitutions (original claims 1 and 2; specification at page 12, lines 28-33 and page 13, lines 14-19), the examiner is unable to locate adequate support in the specification for the combination of said three mutations. Thus there is no indication that the triple substitution comprising R118K, R320K and R458K was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 25-30, 50, 57 and 59-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21, with dependent claims 26-30, 50 and 57 is drawn to "A variant of a parent alpha-amylase". Applicants argue that "a variant" means "non-naturally occurring" (Remarks of 8/23/07, page 5). Claim 59, with dependent claims 60-66, is drawn to "A non-naturally occurring, modified parent alpha-amylase". Therefore, the claims recite the genus of non-naturally occurring alpha-amylases. The art teaches various alpha-amylases having different structures. Some of them are purified from the natural sources and then recombinantly produced. Whether it is purified from a natural source or produced recombinantly, alpha-amylases with identical structures are considered to be the same. Neither art nor the specification disclose properties that would allow to distinguish between alpha-amylases having the same structure. There is no description of properties that would allow to distinguish between naturally occurring and non-naturally occurring alpha-amylase of the same structure.

The specification fails to define those structural or other features of non-naturally occurring alpha-amylases that are commonly possessed by members of the genus that distinguish them from others. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus.

Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50, 57, 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50, 57, 65 and 66 are confusing as reciting "an amino acid sequence shown in SEQ ID NO: 12" because "an" implies several sequences where it appears that only one, i.e. the amino acid sequence of SEQ ID NO:12 is intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 25, 27, 28, 30, 59, 61, 62 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Outtrup et al (A) or (B).

Outtrup et al (A) (US Patent 5,824,531, form PTO-892 mailed 5/24/06) and (B) (US Patent 5,856,164, form PTO-892 mailed 5/24/06) teach *Bacillus* alpha-amylase of SEQ ID NO:2 that is 90% identical to SEQ ID NO:12 of the instant invention and comprises K at positions corresponding to positions 320 and 458 of SEQ ID NO:12. As a chemical compound, alpha-amylase is characterized by its sequence. Alpha-amylase taught by Outtrup et al is a variant of the alpha-amylase of SEQ ID NO:12. There is no way to distinguish between a variant produced by nature and man.

Claims 25, 27, 28, 30, 59, 61, 62 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by following twelve US Patents 6093562, 6187576, 6197565, 6204232, 6287826, 6297038, 6361989, 6486113, 6528298, 6673589, 6867031, 6887986.

The applied references have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. The above patents (form PTO-892 mailed 5/24/06) teach *Bacillus* alpha-amylase having the amino acid sequence that is 90% identical to SEQ ID NO:12 of the instant invention

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and comprises K at positions corresponding to positions 320 and 458 of SEQ ID NO:12.

As a chemical compound, alpha-amylase is characterized by its sequence. Alpha-amylase taught in said patents is a variant of the alpha-amylase of SEQ ID NO:12.

There is no way to distinguish between a variant produced by nature and man.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 27, 28, 30, 59, 61, 62 and 64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6093562, 6187576, 6197565, 6204232, 6297038, 6673589 (see Final Office action mailed 2/23/07).

Although the conflicting claims are not identical, they are not patentably distinct from each other because patent claims are drawn alpha-amylase having the amino acid sequence that is 90% identical to SEQ ID NO:12 of the instant invention and comprises K at positions corresponding to positions 320 and 458 of SEQ ID NO:12.

Response to Arguments

Applicant's arguments filed August 23, 2007 have been fully considered but they are not persuasive.

With regards to all rejections, Applicants argue that the term "variant" and "substitution" distinguishes the claimed alpha-amylases from the wild-type enzyme of Outtrup et al which is neither a "variant" nor does have a "substitution" at the recited position" (Remarks, page 5). This is not persuasive because the enzyme taught by Outtrup et al does have a substitution at the recited position as compared to SERQ ID NO:12. When examining the structure, there is no way to distinguish between naturally and non-naturally occurring enzymes. Furthermore, the term "variant" does not have a patentable weight because it does not provide any structural limitations. The same compound, i.e. alpha-amylase, can be named differently but it remains the same compound and cannot be patented just because it is named differently.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

September 4, 2007